**REMARKS**

The Office Action dated January 12, 2007 has been carefully reviewed and the following comments are made in response thereto. In view of the following remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Claims 6, 7, 10, and 11 are pending in the instant application. Claims 6, 7, 10, and 11 are rejected. Applicants have amended claims 6 and 7. Without prejudice or disclaimer, Applicants have canceled claim 10. Claim 6 has been amended (1) to recite colitis, which is the technical term for colonic inflammation, (2) to recite bacteria instead of bacterium, and (3) to properly italicize the name of the bacterial species. Applicants have amended claim 7 to incorporate features of claim 10. Support for the amendment to claim 6 is found on page 8, line 21 of the specification.

The Objection to claim 10 is moot

Claim 10 is objected to under 37 C.F.R. 1.75(c) as being of improper dependent form for failing to further limit the subject matter of the previous claim. Without acquiescing to the merits of the rejection and for the sole purpose of advancing prosecution, Applicants have canceled claim 10 thereby rendering the objection moot.

The Rejection under 35 U.S.C. § 112, first paragraph should be withdrawn

Claims 6, 7, 10 and 11 are rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. The Office Action alleges that the specification, while enabling for a method of treating colonic inflammation due to colitis comprising administration of an effective amount of a composition comprising lactic acid bacteria of the species *Lactobacillus farciminis*, does not reasonably provide enablement for any method treating colonic inflammation and/or chronic hypersensitivity due to any other pathology.

As the Examiner is aware, "[t]he test for enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the patent coupled with information known in the art without undue experimentation" *In re Wands*, 858 F.2d 721, 737 (Fed. Cir. 1988). Applicants respectfully submit the claims as amended are clearly enabled.

Prior to discussing the merits of the rejection, Applicants note that claim 10 has been canceled without prejudice and disclaimer. Therefore the rejection of claim 10 under 35 U.S.C. § 112, first paragraph, is moot.

The instant disclosure is related to the use of *L. farciminis* for treating (1) colitis, which is generally associated with intestinal chronic inflammatory diseases such as *e.g.*, Crohn's disease and ulcerative colitis, and (2) colonic hypersensitivity, which may result from colonic inflammation, or from other factors such as *e.g.*, stress. Colonic hypersensitivity is known to be often associated with irritable bowel syndrome. Claim 6, as amended, is directed to a method of treating colitis and/or colonic hypersensitivity to distension by administration of an effective amount a composition containing *L. farciminis*. Claim 7 specifies that the colitis and/or colonic hypersensitivity are a result of a pathology associated with Crohn's disease, hemorrhagic rectocolitis, or irritable bowel syndrome. Claim 11 specifies that the composition is a foodstuff or dietary supplement.

The term "colitis" has a special meaning in the art. Claim 6, as amended, recites colitis instead of colonic inflammation. This amendment is clearly supported by the specification, *see* page 8, line 21, and more importantly, reflects accepted medical terminology for inflammation of the colon. *Dorland's Illustrated Medical Dictionary*, 375 (29th ed. 2000) (excerpt of relevant pages attached). Those of skill in the art would recognize that the term "colitis" encompasses several specific diseases, all of which include the symptom of colonic inflammation. These diseases include ulcerative colitis and Crohn's disease. *See Dorland's* at 375. One of skill in the art would recognize that "ulcerative colitis" is an alternate name for "hemorrhagic rectocolitis" (*see* attached definition of "ulcerative colitis" from PharmGKB, The Pharmacogenomics Knowledge Base supported by NIH/NIGMS). Thus, one of skill in the art would understand the term "colitis" to encompass Crohn's disease and hemorrhagic rectocolitis.

As amended, the claims are clearly enabled by the specification. The specification discloses that *L. farciminis* is active *in vivo* in reducing the inflammation of the colon and on reducing visceral pain (*see* page 3, lines 35 to 40). The specification also discloses use of *L. farciminis* to treat colitis and/or colonic hypersensitivity to distention due to *e.g.*, "Crohn's disease, hemorrhagic rectocolitis, functional digestive disorders (irritable bowel syndrome and nonulcerative dyspepsia) and the like" (*see* page 6, line 19 to page 7, line 11). The specification further discloses that the treatment is achieved by administering a composition containing *L. farciminis* by *e.g.*, oral administration and in the form of food (*see* page 7, lines 13 to 38) and a preferred administration dose is also disclosed (*see* page 8, lines 4 to 5). In addition, the specification discloses a mechanism by which the invention is thought to work – namely production of nitric oxide in the digestive tube, which exerts a therapeutic effect, in particular, an anti-inflammatory effect, and an effect on pain related to visceral distension (*see* page 6, lines 13 to 16). The specification also cites to *in vitro* and human studies by others in the art showing the efficacy of other microorganisms to treat colitis (*see* page 2, lines 20 to page 3, line 22).

Based on that disclosure in the specification, one of skill in the art can make and use the claimed invention without undue experimentation. In other words, one of skill in the art would be able to (1) administer a composition containing *L. farciminis* to an individual suffering from chronic colitis and/or colonic hypersensitivity to distention due to Crohn's disease, hemorrhagic rectocolitis, or irritable bowel syndrome (2) and then monitor the patient for subsidence of colitis and/or colonic hypersensitivity. It is clearly within the skill in the art to make such a composition, *e.g.*, of *L. farciminis* in fermented dairy products. Furthermore, administration, particularly via ingestion of food, is well within the skill of the art. Thus, even without considering the examples, the claims are clearly enabled.

The Office Action alleges that the claims are not enabled in part because: (1) the specification does not provide any correlation between the animal data shown (animal models for colitis) and other etiologies or diseases; and (2) the absence of working examples suggesting treatment of colonic inflammation and/or colonic hypersensitivity due to distention due to any pathology other than colitis. Applicants respectfully note "[c]ompliance with the enablement requirement does not turn on whether an example is disclosed." *See* M.P.E.P. 2164.02. In addition, in *Gould*, the court stated that an applicant need not have actually reduced the invention to practice prior to filing. *Gould v. Quigg,* 822 F.2d 1074, 1078 (Fed. Cir. 1987). Further, the specification need not contain an example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without undue experimentation. *In re Borkowski,* 422 F.2d 904, 908 (CCPA 1970). As discussed above, the application provides sufficient teaching throughout the specification to enable the skilled artisan to practice the invention without undue experimentation.

Moreover, the specification goes even further. The examples recited in the specification prove that *L. farciminis* can be used for treating colitis and/or chronic hypersensitivity based on studies in animal models. In the Examples, the 2, 4, 6-trinitrobenzene sulfonic acid (TNBS) -induced model of chronic inflammation of the rat colon was used to determine the efficacy of *L. farciminis* for the treatment of colitis and chronic hypersensitivity. This animal model is well accepted within the art for the study of both colitis and chronic hypersensitivity. To support that proposition, Applicants have enclosed exemplary abstracts of articles from PUBMED searches (1) with the search term "TNBS colitis" (*see* Annex 1) and (2) for TNBS and colonic hypersensitivity (*see* Annex 3).

Since its first description in 1989, the TNBS model has become a well-known model for the study of inflammatory bowel disease. Sreekant Murthy, *Animal Models in inflammatory bowel disease, in* 2 *IN VIVO* MODELS OF INFLAMMATION, 137 (Christopher S. Stevenson *et al.* eds., 2 ed. 2006) (attached as Annex 2). The two most common types of inflammatory bowel diseases are ulcerative colitis and

Crohn's disease. *See* Murthy at 137. The TNBS model is used because the histopathological and cytokine profile observed in the *in vivo* model are reminiscent of the pattern of injury observed in inflammatory bowel disease. *See* Murthy at 151; *see also* R. Shoda *et al.*, Therapeutic efficacy of N-3 polyunsaturated fatty acid in experimental Crohn's diseases, *J. Gastroenterol.* 30 Suppl. 8: 98-101 (1995) (TNBS considered experimental for Crohn's disease) (Abstract enclosed).

Applicants respectfully submit that the Examples, in particular Examples 1 and 3, provide further exemplary support for the enablement of the pending claims. Example 1 shows that administration of *L. farciminis* is effective for the treatment of colitis (*see* page 8, line 16 to page 15, line 9). Example 3 of the instant application shows that administration of *L. farciminis* is effective for treatment of colonic hypersensitivity induced by inflammation or by stress conditions (*see* page 16, line 22 to page 20, line 12). Even though these results are based on an *in vivo* rat model, one of skill in the art would understand that these Examples teach that *L. farciminis* can be administered for the treatment of colitis and/or colonic hypersensitivity to distension in patients suffering from Crohn's disease, hemorrhagic rectocolitis, or irritable bowel syndrome.

Accordingly, the specification enables claims 6, 7, and 11. Applicants therefore respectfully request withdrawal of the rejection of these claims under 35 U.S.C. § 112, first paragraph.

The Rejection under 35 U.S.C. § 112, second paragraph should be withdrawn

Claims 6, 7, 10 and 11 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention.

Claim 6 is alleged to be rendered vague and indefinite by use of the term "bacterium." Without acquiescing to the merits of the rejection and for the sole purpose of advancing prosecution, Applicants have amended claim 6 to recite "bacteria" instead of "bacterium." Claim 7 is alleged to be rendered vague and indefinite by use of the phrase "chronic inflammatory pathology of the intestine." Without acquiescing to the merits of the rejection and for the sole purpose of advancing prosecution, Applicants have amended claim 7 to no longer recite the phrase "chronic inflammatory pathology of the intestine." Since the claims no longer recite the allegedly indefinite terms, the rejection of the claims is moot. Therefore, Applicants respectfully request withdrawal of the rejection of claims 6, 7 and 11 under 35 U.S.C. § 112, second paragraph.

## CONCLUSION

Applicants respectfully request that the above remarks be made of record in the file history of the present application. It is respectfully submitted that all claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

Except for issues payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310.

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Morgan, Lewis & Bockius LLP
Customer No. **09629**
1111 Pennsylvania Ave., NW
Washington, D.C. 20004
Tel: 202-739-3000
Fax: 202-739-3001

Respectfully submitted
**Morgan, Lewis & Bockius LLP**

Elizabeth C. Weimar
Registration No. 44,478